Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.''

Pub. L. 102–571, title I, § 104, Oct. 29, 1992, 106 Stat. 4498, provided that:

''(a) FIRST REPORT.—Within 60 days after the end of each fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart], the Secretary of Health and Human Services shall submit a report stating the Food and Drug Administration's progress in achieving the goals identified in section 102(3) of this Act [set out as a note above] during such fiscal year and that agency's future plans for meeting such goals.

''(b) SECOND REPORT.—Within 120 days after the end of each fiscal year during which such fees are collected, the Secretary of Health and Human Services shall submit a report on the implementation of the authority for such fees during such fiscal year and on the use the Food and Drug Administration made of the fees collected during such fiscal year for which the report is made.

''(c) COMMITTEES.—The reports described in subsections (a) and (b) shall be submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.''

ANIMAL DRUG USER FEE STUDY

Pub. L. 102–571, title I, § 108, Oct. 29, 1992, 106 Stat. 4500, directed Secretary, in consultation with manufacturers of animal drug products and other interested persons, to undertake study to evaluate whether, and under what conditions, to impose user fees to supplement appropriated funds in order to improve process of reviewing applications (including abbreviated and supplemental applications) for new animal drugs under section 360b of this title, and further provided for submission of study to Congress no later than Jan. 4, 1994.

§ 379h. Authority to assess and use drug fees

(a) Types of fees

Beginning in fiscal year 2018, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) Human drug application fee

(A) In general

Each person that submits, on or after September 1, 1992, a human drug application shall be subject to a fee as follows:

(i) A fee established under subsection (c)(5) for a human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required for approval.

(ii) A fee established under subsection (c)(5) for a human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are not required for approval. Such fee shall be half of the amount of the fee established under clause (i).

(B) Payment

The fee required by subparagraph (A) shall be due upon submission of the application.

(C) Exception for previously filed application

If a human drug application was submitted by a person that paid the fee for such application, was accepted for filing, and was not approved or was withdrawn (without a waiver), the submission of a human drug application for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(D) Refund of fee if application refused for filing or withdrawn before filing

The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any application which is refused for filing or withdrawn without a waiver before filing.

(E) Fees for applications previously refused for filing or withdrawn before filing

A human drug application that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the fee is waived or reduced under subsection (d).

(F) Exception for designated orphan drug

A human drug application for a prescription drug product that has been designated as a drug for a rare disease or condition pursuant to section 360bb of this title shall not be subject to a fee under subparagraph (A), unless the human drug application includes an indication for other than a rare disease or condition.

(G) Refund of fee if application withdrawn

If an application is withdrawn after the application was filed, the Secretary may refund the fee or a portion of the fee if no substantial work was performed on the application after the application was filed. The Secretary shall have the sole discretion to refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

(2) Prescription drug program fee

(A) In general

Except as provided in subparagraphs (B) and (C), each person who is named as the applicant in a human drug application, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay the annual prescription drug program fee established for a fiscal year under subsection (c)(5) for each prescription drug product that is identified in such a human drug application approved as of October 1 of such fiscal year. Such fee shall be due on the later of the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.

(B) Exception for certain prescription drug products

A prescription drug program fee shall not be assessed for a prescription drug product under subparagraph (A) if such product is—

(i) identified on the list compiled under section 355(j)(7) of this title with a potency described in terms of per 100 mL;

(ii) the same product as another product that—

(I) was approved under an application filed under section 355(b) or 355(j) of this title; and

(II) is not in the list of discontinued products compiled under section 355(j)(7) of this title;

(iii) the same product as another product that was approved under an abbreviated application filed under section 357 of this title (as in effect on the day before November 21, 1997); or

(iv) the same product as another product that was approved under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.

(C) Limitation

A person who is named as the applicant in an approved human drug application shall not be assessed more than 5 prescription drug program fees for a fiscal year for prescription drug products identified in such approved human drug application.

(b) Fee revenue amounts

(1) In general

For each of the fiscal years 2018 through 2022, fees under subsection (a) shall, except as provided in subsections (c), (d), (f), and (g), be established to generate a total revenue amount under such subsection that is equal to the sum of—

(A) the annual base revenue for the fiscal year (as determined under paragraph (3));

(B) the dollar amount equal to the inflation adjustment for the fiscal year (as determined under subsection (c)(1));

(C) the dollar amount equal to the capacity planning adjustment for the fiscal year (as determined under subsection (c)(2));

(D) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(3));

(E) the dollar amount equal to the additional direct cost adjustment for the fiscal year (as determined under subsection (c)(4)); and

(F) additional dollar amounts for each fiscal year as follows:

(i) $20,077,793 for fiscal year 2018.

(ii) $21,317,472 for fiscal year 2019.

(iii) $16,953,329 for fiscal year 2020.

(iv) $5,426,896 for fiscal year 2021.

(v) $2,769,609 for fiscal year 2022.

(2) Types of fees

Of the total revenue amount determined for a fiscal year under paragraph (1)—

(A) 20 percent shall be derived from human drug application fees under subsection (a)(1); and

(B) 80 percent shall be derived from prescription drug program fees under subsection (a)(2).

(3) Annual base revenue

For purposes of paragraph (1), the dollar amount of the annual base revenue for a fiscal year shall be—

(A) for fiscal year 2018, $878,590,000; and

(B) for fiscal years 2019 through 2022, the dollar amount of the total revenue amount established under paragraph (1) for the previous fiscal year, not including any adjustments made under subsection (c)(3) or (c)(4).

(c) Adjustments; annual fee setting

(1) Inflation adjustment

(A) In general

For purposes of subsection (b)(1)(B), the dollar amount of the inflation adjustment to the annual base revenue for each fiscal year shall be equal to the product of—

(i) such annual base revenue for the fiscal year under subsection (b)(1)(A); and

(ii) the inflation adjustment percentage under subparagraph (B).

(B) Inflation adjustment percentage

The inflation adjustment percentage under this subparagraph for a fiscal year is equal to the sum of—

(i) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 379g(6) of this title) for the first 3 years of the preceding 4 fiscal years; and

(ii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 379g(6) of this title) for the first 3 years of the preceding 4 fiscal years.

(2) Capacity planning adjustment

(A) In general

For each fiscal year, after the annual base revenue established in subsection (b)(1)(A) is adjusted for inflation in accordance with paragraph (1), such revenue shall be adjusted further for such fiscal year, in accordance with this paragraph, to reflect changes in the resource capacity needs of the Secretary for the process for the review of human drug applications.

(B) Interim methodology

(i) In general

Until the capacity planning methodology described in subparagraph (C) is effective, the adjustment under this paragraph for a fiscal year shall be based on the product of—

(I) the annual base revenue for such year, as adjusted for inflation under paragraph (1); and

(II) the adjustment percentage under clause (ii).

(ii) Adjustment percentage

The adjustment percentage under this clause for a fiscal year is the weighted change in the 3-year average ending in the most recent year for which data are available, over the 3-year average ending in the previous year, for—

(I) the total number of human drug applications, efficacy supplements, and manufacturing supplements submitted to the Secretary;

(II) the total number of active commercial investigational new drug applications; and

(III) the total number of formal meetings scheduled by the Secretary, and written responses issued by the Secretary in lieu of such formal meetings, as identified in section I.H of the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017.

(C) Capacity planning methodology

(i) Development; evaluation and report

The Secretary shall obtain, through a contract with an independent accounting or consulting firm, a report evaluating options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the process for the review of human drug applications. The capacity planning methodological options and recommendations presented in such report shall utilize and be informed by personnel time reporting data as an input. The report shall be published for public comment no later than the end of fiscal year 2020.

(ii) Establishment and implementation

After review of the report described in clause (i) and any public comments thereon, the Secretary shall establish a capacity planning methodology for purposes of this paragraph, which shall—

(I) replace the interim methodology under subparagraph (B);

(II) incorporate such approaches and attributes as the Secretary determines appropriate; and

(III) be effective beginning with the first fiscal year for which fees are set after such capacity planning methodology is established.

(D) Limitation

Under no circumstances shall an adjustment under this paragraph result in fee revenue for a fiscal year that is less than the sum of the amounts under subsections (b)(1)(A) (the annual base revenue for the fiscal year) and (b)(1)(B) (the dollar amount of the inflation adjustment for the fiscal year).

(E) Publication in Federal Register

The Secretary shall publish in the Federal Register notice under paragraph (5) of the fee revenue and fees resulting from the adjustment and the methodologies under this paragraph.

(3) Operating reserve adjustment

(A) Increase

For fiscal year 2018 and subsequent fiscal years, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenue and fees if such an adjustment is necessary to provide for not more than 14 weeks of operating reserves of carryover user fees for the process for the review of human drug applications.

(B) Decrease

If the Secretary has carryover balances for such process in excess of 14 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 14 weeks of such operating reserves.

(C) Notice of rationale

If an adjustment under subparagraph (A) or (B) is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under paragraph (5) establishing fee revenue and fees for the fiscal year involved.

(4) Additional direct cost adjustment

(A) In general

The Secretary shall, in addition to adjustments under paragraphs (1), (2), and (3), further increase the fee revenue and fees—

(i) for fiscal year 2018, by $8,730,000; and

(ii) for fiscal year 2019 and subsequent fiscal years, by the amount determined under subparagraph (B).

(B) Amount

The amount determined under this subparagraph is—

(i) $8,730,000, multiplied by

(ii) the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All Items; Annual Index) for the most recent year of available data, divided by such Index for 2016.

(5) Annual fee setting

The Secretary shall, not later than 60 days before the start of each fiscal year that begins after September 30, 2017—

(A) establish, for each such fiscal year, human drug application fees and prescription drug program fees under subsection (a), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection; and

(B) publish such fee revenue and fees in the Federal Register.

(6) Limit

The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of human drug applications.

(d) Fee waiver or reduction

(1) In general

The Secretary shall grant to a person who is named as the applicant in a human drug application a waiver from or a reduction of one or more fees assessed to that person under subsection (a) where the Secretary finds that—

(A) such waiver or reduction is necessary to protect the public health,

(B) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances, or

(C) the applicant involved is a small business submitting its first human drug application to the Secretary for review.

(2) Considerations

In determining whether to grant a waiver or reduction of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant involved and any affiliate of the applicant.

(3) Rules relating to small businesses

(A) "Small business" defined

In paragraph (1)(C), the term ''small business'' means an entity that has fewer than 500 employees, including employees of affiliates, and that does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce.

(B) Waiver of application fee

The Secretary shall waive under paragraph (1)(C) the application fee for the first human drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay application fees for all subsequent human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business.

(e) Effect of failure to pay fees

A human drug application or supplement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all such fees owed by such person have been paid.

(f) Limitations

(1) In general

Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 1997 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

(2) Authority

If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for human drug applications and prescription drug program fees at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(3) Limitation

Beginning on October 1, 2023, the authorities under section 379g(7)(C) of this title shall include only expenditures for leasing and necessary scientific equipment.

(g) Crediting and availability of fees

(1) In general

Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications.

(2) Collections and appropriation acts

(A) In general

The fees authorized by this section—

(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year, and

(ii) shall be available to defray increases in the costs of the resources allocated for the process for the review of human drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997 multiplied by the adjustment factor.

(B) Compliance

The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of human drug applications—

(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and

fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in such subparagraph; and

(II) such costs are not more than 5 percent below the level specified in such subparagraph.

(C) Provision for early payments

Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) Authorization of appropriations

For each of the fiscal years 2018 through 2022, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under subsection (c).

(h) Collection of unpaid fees

In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31.

(i) Written requests for waivers, reductions, and refunds

To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

(j) Construction

This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in the process of the review of human drug applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(k) Orphan drugs

(1) Exemption

A drug designated under section 360bb of this title for a rare disease or condition and approved under section 355 of this title or under section 262 of title 42 shall be exempt from prescription drug program fees under this section, if the drug meets all of the following conditions:

(A) The drug meets the public health requirements contained in this chapter as such requirements are applied to requests for waivers for prescription drug program fees.

(B) The drug is owned or licensed and is marketed by a company that had less than $50,000,000 in gross worldwide revenue during the previous year.

(2) Evidence of qualification

An exemption under paragraph (1) applies with respect to a drug only if the applicant involved submits a certification that its gross annual revenues did not exceed $50,000,000 for the preceding 12 months before the exemption was requested.

(June 25, 1938, ch. 675, § 736, as added Pub. L. 102–571, title I, § 103, Oct. 29, 1992, 106 Stat. 4494; amended Pub. L. 105–115, title I, § 103(a)–(g), Nov. 21, 1997, 111 Stat. 2299–2304; Pub. L. 107–109, § 5(a), Jan. 4, 2002, 115 Stat. 1413; Pub. L. 107–188, title V, § 504, June 12, 2002, 116 Stat. 689; Pub. L. 110–85, title I, § 103(a)–(h)(1), Sept. 27, 2007, 121 Stat. 826–832; Pub. L. 112–144, title I, § 103, July 9, 2012, 126 Stat. 996; Pub. L. 115–52, title I, § 102(a)(1), (b)–(h), title IX, § 905(b)(1), Aug. 18, 2017, 131 Stat. 1007–1012, 1090.)

TERMINATION OF SECTION

For termination of section by section 104(a) of Pub. L. 115–52, see Termination Date note below.

Editorial Notes

REFERENCES IN TEXT

Section 357 of this title, referred to in subsec. (a)(2)(B)(iii), was repealed by Pub. L. 105–115, title I, § 125(b)(1), Nov. 21, 1997, 111 Stat. 2325.

The Drug Price Competition and Patent Term Restoration Act of 1984, referred to in subsec. (a)(2)(B)(iv), is Pub. L. 98–417, Sept. 24, 1984, 98 Stat. 1585. For complete classification of this Act to the Code, see Short Title of 1984 Amendment note set out under section 301 of this title and Tables.

Section 101(b) of the Prescription Drug User Fee Amendments of 2017, referred to in subsec. (c)(2)(B)(ii)(III), is section 101(b) of Pub. L. 115–52, set out as a note under section 379g of this title.

AMENDMENTS

2017—Subsec. (a). Pub. L. 115–52, § 102(a)(1)(A), substituted ''fiscal year 2018'' for ''fiscal year 2013'' in introductory provisions.

Subsec. (a)(1). Pub. L. 115–52, § 102(a)(1)(B), (C), struck out ''and supplement'' before ''fee'' in heading and struck out ''or a supplement'' and ''or supplement'' wherever appearing in text.

Subsec. (a)(1)(A)(i). Pub. L. 115–52, § 102(a)(1)(D)(i), substituted ''(c)(5)'' for ''(c)(4)''.

Subsec. (a)(1)(A)(ii). Pub. L. 115–52, § 102(a)(1)(C), (D)(ii), substituted ''A fee established under subsection (c)(5) for a human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are not required for approval.'' for ''A fee established under subsection (c)(4) for a human drug application for which clinical data with respect to safety or effectiveness are not required for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required.''

Subsec. (a)(1)(C). Pub. L. 115–52, § 102(a)(1)(E), struck out ''or supplement'' after ''application'' in heading.

Subsec. (a)(1)(F). Pub. L. 115–52, § 102(a)(1)(F), struck out ''or indication'' after ''drug'' in heading and ''A supplement proposing to include a new indication for a rare disease or condition in a human drug application shall not be subject to a fee under subparagraph (A), if the drug has been designated pursuant to section 360bb of this title as a drug for a rare disease or condition with regard to the indication proposed in such supplement.'' in text.

Subsec. (a)(2). Pub. L. 115–52, § 102(a)(1)(G)–(I), redesignated par. (3) as (2), substituted ''Prescription drug program fee'' for ''Prescription drug product fee'' in heading, and struck out former par. (2) which related to prescription drug establishment fee.

Subsec. (a)(2)(A). Pub. L. 115–52, § 102(a)(1)(J), substituted ''Except as provided in subparagraphs (B) and

(C), each person who is named as the applicant in a human drug application, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay the annual prescription drug program fee established for a fiscal year under subsection (c)(5) for each prescription drug product that is identified in such a human drug application approved as of October 1 of such fiscal year.'' for ''Except as provided in subparagraph (B), each person who is named as the applicant in a human drug application, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay for each such prescription drug product the annual fee established under subsection (c)(4).''

Subsec. (a)(2)(B). Pub. L. 115–52, §102(a)(1)(K), inserted ''for certain prescription drug products'' after ''Exception'' in heading and substituted ''A prescription drug program fee shall not be assessed for a prescription drug product'' for ''A prescription drug product shall not be assessed a fee'' in introductory provisions.

Subsec. (a)(2)(C). Pub. L. 115–52, §102(a)(1)(L), added subpar. (C).

Subsec. (a)(3). Pub. L. 115–52, §102(a)(1)(H), redesignated par. (3) as (2).

Subsec. (b). Pub. L. 115–52, §102(b), amended subsec. (b) generally. Prior to amendment, subsec. (b) related to fee revenue amounts for fiscal years 2013 through 2017.

Subsec. (c). Pub. L. 115–52, §102(c), amended subsec. (c) generally. Prior to amendment, subsec. (c) related to adjustment of revenues for inflation and changes in workload, final year adjustment, setting of annual fee, and limit on total amount of fees charged.

Subsec. (d)(1)(C), (D). Pub. L. 115–52, §102(d)(1), redesignated subpar. (D) as (C) and struck out former subpar. (C) which read as follows: ''the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of human drug applications for such person, or''.

Subsec. (d)(3). Pub. L. 115–52, §102(d)(2), (3), redesignated par. (4) as (3) and struck out former par. (3). Text read as follows: ''In making the finding in paragraph (1)(C), the Secretary may use standard costs.''

Subsec. (d)(3)(A). Pub. L. 115–52, §102(d)(4)(A), substituted ''paragraph (1)(C)'' for ''paragraph (1)(D)''.

Subsec. (d)(3)(B). Pub. L. 115–52, §102(d)(4), substituted ''paragraph (1)(C)'' for ''paragraph (1)(D)'', struck out cl. (i) designation before ''application fees'', substituted a period for ''; and'' after ''qualify as a small business'', and struck out cl. (ii), which read as follows: ''all supplement fees for all supplements to human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business.''

Subsec. (d)(4). Pub. L. 115–52, §102(d)(3), redesignated par. (4) as (3).

Subsec. (e). Pub. L. 115–52, §102(e), substituted ''all such fees'' for ''all fees''.

Subsec. (f)(2). Pub. L. 115–52, §102(f), substituted ''prescription drug program fees'' for ''supplements, prescription drug establishments, and prescription drug products''.

Subsec. (f)(3). Pub. L. 115–52, §905(b)(1), added par. (3).

Subsec. (g)(3). Pub. L. 115–52, §102(g)(1), substituted ''2018 through 2022'' for ''2013 through 2017'' and struck out ''and paragraph (4) of this subsection'' after ''subsection (c)''.

Subsec. (g)(4). Pub. L. 115–52, §102(g)(2), struck out par. (4). Prior to amendment, text read as follows: ''If the sum of the cumulative amount of fees collected under this section for the fiscal years 2013 through 2015 and the amount of fees estimated to be collected under this section for fiscal year 2016 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2013 through 2016, the excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2017.''

Subsec. (k)(1). Pub. L. 115–52, §102(h), substituted ''prescription drug program fees'' for ''product and establishment fees'' in two places.

2012—Subsec. (a). Pub. L. 112–144, §103(1)(A), substituted ''fiscal year 2013'' for ''fiscal year 2008'' in introductory provisions.

Subsec. (a)(1)(A). Pub. L. 112–144, §103(1)(B), substituted ''(c)(4)'' for ''(c)(5)'' in cls. (i) and (ii).

Subsec. (a)(2)(A). Pub. L. 112–144, §103(1)(C), substituted ''(c)(4)'' for ''(c)(5)'' and ''due on the later of the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section'' for ''payable on or before October 1 of each year'' in concluding provisions.

Subsec. (a)(3)(A). Pub. L. 112–144, §103(1)(D)(i), substituted ''subsection (c)(4)'' for ''subsection (c)(5)'' and ''due on the later of the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section.'' for ''payable on or before October 1 of each year.''

Subsec. (a)(3)(B). Pub. L. 112–144, §103(1)(D)(ii), amended subpar. (B) generally. Prior to amendment, text read as follows: ''A prescription drug product shall not be assessed a fee under subparagraph (A) if such product is identified on the list compiled under section 355(j)(7)(A) of this title with a potency described in terms of per 100 mL, or if such product is the same product as another product approved under an application filed under section 355(b) or 355(j) of this title, under an abbreviated application filed under section 357 of this title (as in effect on the day before November 21, 1997), or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.''

Subsec. (b)(1). Pub. L. 112–144, §103(2)(A)(i), substituted ''fiscal years 2013 through 2017'' for ''fiscal years 2008 through 2012'' in introductory provisions.

Subsec. (b)(1)(A). Pub. L. 112–144, §103(2)(A)(ii), substituted ''$693,099,000;'' for ''$392,783,000; and''.

Subsec. (b)(1)(B), (C). Pub. L. 112–144, §103(2)(A)(iii), added subpars. (B) and (C) and struck out former subpar. (B) which read as follows: ''an amount equal to the modified workload adjustment factor for fiscal year 2007 (as determined under paragraph (3)).''

Subsec. (b)(3), (4). Pub. L. 112–144, §103(2)(B), added par. (3) and struck out former pars. (3) and (4) which related to the modified workload adjustment factor for fiscal year 2007 and additional fee revenues for drug safety for fiscal years 2008 through 2012, respectively.

Subsec. (c). Pub. L. 112–144, §103(3), added subsec. (c) and struck out former subsec. (c) which related to inflation adjustment for fiscal year 2009 and subsequent fiscal years, workload adjustment for fiscal year 2009 and subsequent fiscal years, rent and rent-related cost adjustment for fiscal year 2010 and each subsequent fiscal year, final year adjustment for fiscal year 2012, annual fee setting for each fiscal year that began after Sept. 30, 2007, and the limit on the total amount of fees charged for a fiscal year.

Subsec. (g)(1). Pub. L. 112–144, §103(4)(A), substituted ''Subject to paragraph (2)(C), fees authorized'' for ''Fees authorized''.

Subsec. (g)(2)(A)(i). Pub. L. 112–144, §103(4)(B)(i), substituted ''subject to subparagraph (C), shall be collected and available'' for ''shall be retained''.

Subsec. (g)(2)(A)(ii). Pub. L. 112–144, §103(4)(B)(ii), substituted ''shall be available'' for ''shall only be collected and available''.

Subsec. (g)(2)(C). Pub. L. 112–144, §103(4)(B)(iii), added subpar. (C).

Subsec. (g)(3). Pub. L. 112–144, §103(4)(C), substituted ''fiscal years 2013 through 2017'' for ''fiscal years 2008 through 2012''.

Subsec. (g)(4). Pub. L. 112–144, §103(4)(D), substituted ''fiscal years 2013 through 2015'' for ''fiscal years 2008

through 2010'', ''fiscal year 2016'' for ''fiscal year 2011'', ''fiscal years 2013 through 2016'' for ''fiscal years 2008 through 2011'', and ''fiscal year 2017'' for ''fiscal year 2012''.

2007—Subsec. (a). Pub. L. 110–85, §103(a)(1), substituted ''2008'' for ''2003'' in introductory provisions.

Subsec. (a)(1)(A). Pub. L. 110–85, §103(g), substituted ''(c)(5)'' for ''(c)(4)'' in cls. (i) and (ii).

Subsec. (a)(1)(D). Pub. L. 110–85, §103(a)(2)(A), inserted ''or withdrawn before filing'' after ''refused for filing'' in heading and ''or withdrawn without a waiver before filing'' before period at end of text.

Subsec. (a)(1)(E) to (G). Pub. L. 110–85, §103(a)(2)(B), (C), added subpar. (E) and redesignated former subpars. (E) and (F) as (F) and (G), respectively.

Subsec. (a)(2)(A). Pub. L. 110–85, §103(a)(3)(A), (g), substituted ''subparagraphs (B) and (C)'' for ''subparagraph (B)'' in introductory provisions and ''(c)(5)'' for ''(c)(4)'' in concluding provisions.

Subsec. (a)(2)(C). Pub. L. 110–85, §103(a)(3)(B), added subpar. (C).

Subsec. (a)(3)(A). Pub. L. 110–85, §103(g), substituted ''(c)(5)'' for ''(c)(4)''.

Subsec. (b). Pub. L. 110–85, §103(b), amended subsec. (b) generally, substituting provisions contained in pars. (1) to (4) relating to fee revenue amounts for fiscal years 2008 through 2012 for undesignated provisions relating to fee schedules for fiscal years 2003 to 2007.

Subsec. (c)(1). Pub. L. 110–85, §103(c)(1), amended par. (1) by substituting ''For fiscal year 2009 and subsequent fiscal years, the revenues established in subsection (b)'' for ''The revenues established in subsection (b)'' in introductory provisions, adding subpar. (C), and substituting ''fiscal year 2008'' for ''fiscal year 2003'' in concluding provisions.

Subsec. (c)(2). Pub. L. 110–85, §103(c)(2)(A), substituted ''For fiscal year 2009 and subsequent fiscal years,'' for ''Beginning with fiscal year 2004,'' in introductory provisions.

Subsec. (c)(2)(A). Pub. L. 110–85, §103(c)(2)(B), substituted ''human drug applications (adjusted for changes in review activities, as described in the notice that the Secretary is required to publish in the Federal Register under this subparagraph), efficacy supplements, and manufacturing supplements submitted to the Secretary, and the change in the total number of active commercial investigational new drug applications (adjusted for changes in review activities, as so described) during the most recent 12-month period for which data on such submissions is available.'' for ''human drug applications, commercial investigational new drug applications, efficacy supplements, and manufacturing supplements submitted to the Secretary.'' in first sentence.

Subsec. (c)(2)(B). Pub. L. 110–85, §103(c)(2)(C), inserted at end ''Any adjustment for changes in review activities made in setting fees and revenue amounts for fiscal year 2009 may not result in the total workload adjustment being more than 2 percentage points higher than it would have been in the absence of the adjustment for changes in review activities.''

Subsec. (c)(2)(C). Pub. L. 110–85, §103(c)(2)(D), added subpar. (C).

Subsec. (c)(3). Pub. L. 110–85, §103(c)(3), added par. (3). Former par. (3) redesignated (4).

Subsec. (c)(4). Pub. L. 110–85, §103(c)(3)(A), (4), redesignated par. (3) as (4) and amended it generally. Prior to amendment, text read as follows: ''For fiscal year 2007, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenues and fees established in subsection (b) of this section if such an adjustment is necessary to provide for not more than three months of operating reserves of carryover user fees for the process for the review of human drug applications for the first three months of fiscal year 2008. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2007. If the Secretary has carryover balances for such process in excess of three months of such operating reserves, the adjustment under this paragraph shall not be made.'' Former par. (4) redesignated (5).

Subsec. (c)(5). Pub. L. 110–85, §103(c)(3)(A), (5), redesignated par. (4) as (5) and substituted ''2007'' for ''2002''. Former par. (5) redesignated (6).

Subsec. (c)(6). Pub. L. 110–85, §103(c)(3)(A), redesignated par. (5) as (6).

Subsec. (d)(1). Pub. L. 110–85, §103(d)(1), inserted ''to a person who is named as the applicant in a human drug application'' after ''The Secretary shall grant'' and ''to that person'' after ''one or more fees assessed'' in introductory provisions.

Subsec. (d)(2), (3). Pub. L. 110–85, §103(d)(2), (3), added par. (2) and redesignated former par. (2) as (3). Former par. (3) redesignated (4).

Subsec. (d)(4). Pub. L. 110–85, §103(d)(2), redesignated par. (3) as (4).

Subsec. (d)(4)(A). Pub. L. 110–85, §103(d)(4), inserted before period at end '', and that does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce''.

Subsec. (g)(1). Pub. L. 110–85, §103(h)(1), substituted ''Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended.'' for ''Fees collected for a fiscal year pursuant to subsection (a) of this section shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriation Acts until expended without fiscal year limitation.''

Subsec. (g)(3). Pub. L. 110–85, §103(e)(1), amended par. (3) generally. Prior to amendment, par. (3) authorized appropriations for fiscal years 2003 to 2007.

Subsec. (g)(4). Pub. L. 110–85, §103(e)(2), reenacted heading without change and amended text generally. Prior to amendment, text read as follows: ''Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.''

Subsec. (k). Pub. L. 110–85, §103(f), added subsec. (k).

2002—Subsec. (a). Pub. L. 107–188, §504(a)(1), substituted ''fiscal year 2003'' for ''fiscal year 1998'' in introductory provisions.

Subsec. (a)(1)(A)(i). Pub. L. 107–188, §504(a)(2)(A), substituted ''under subsection (c)(4)'' for ''in subsection (b)''.

Subsec. (a)(1)(A)(ii). Pub. L. 107–188, §504(a)(2), substituted ''under subsection (c)(4)'' for ''in subsection (b)'' and inserted ''Such fee shall be half of the amount of the fee established under clause (i).'' at end.

Subsec. (a)(1)(F), (G). Pub. L. 107–109 redesignated subpar. (G) as (F) and struck out heading and text of former subpar. (F). Text read as follows: ''A supplement to a human drug application proposing to include a new indication for use in pediatric populations shall not be assessed a fee under subparagraph (A).''

Subsec. (a)(2)(A). Pub. L. 107–188, §504(a)(3), in concluding provisions, substituted ''under subsection (c)(4)'' for ''in subsection (b)'' and ''payable on or before October 1'' for ''payable on or before January 31''.

Subsec. (a)(3)(A). Pub. L. 107–188, §504(a)(4)(A), amended heading and text of subpar. (A) generally. Prior to amendment, text read as follows: ''Except as provided in subparagraph (B), each person—

''(i) who is named as the applicant in a human drug application for a prescription drug product which has been submitted for listing under section 360 of this title, and

''(ii) who, after September 1, 1992, had pending before the Secretary a human drug application or supplement,

shall pay for each such prescription drug product the annual fee established in subsection (b) of this section. Such fee shall be payable for the fiscal year in which the product is first submitted for listing under section 360 of this title, or is submitted for relisting under section 360 of this title if the product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.''

Subsec. (a)(3)(B). Pub. L. 107–188, §504(a)(4)(B), substituted ''A prescription drug product shall not be assessed a fee under subparagraph (A) if such product is identified on the list compiled under section 355(j)(7)(A) of this title with a potency described in terms of per 100 mL, or if such product is the same product as another product approved under an application filed under section 355(b)'' for ''The listing of a prescription drug product under section 360 of this title shall not require the person who listed such product to pay the fee prescribed by subparagraph (A) if such product is the same product as a product approved under an application filed under section 355(b)(2)''.

Subsec. (b). Pub. L. 107–188, §504(b), amended heading and text of subsec. (b) generally, substituting ''Fee revenue amounts'' for ''Fee amounts'' in heading and substituting fee schedules for fiscal years 2003 to 2007 for fee provisions relating to fiscal years 1998 to 2002.

Subsec. (c)(1). Pub. L. 107–188, §504(c)(1)(A), (D), substituted ''revenues'' for ''fees and total fee revenues'' in introductory provisions and ''fiscal year 2003'' for ''fiscal year 1997'' in concluding provisions.

Subsec. (c)(1)(A). Pub. L. 107–188, §504(c)(1)(B), struck out ''during the preceding fiscal year'' before ''in the Consumer Price Index'' and substituted ''for the 12 month period ending June 30 preceding the fiscal year for which fees are being established, or'' for '', or''.

Subsec. (c)(1)(B). Pub. L. 107–188, §504(c)(1)(C), substituted ''for the previous fiscal year'' for ''for such fiscal year''.

Subsec. (c)(2) to (5). Pub. L. 107–188, §504(c)(2)–(4), added pars. (2) and (3), redesignated former pars. (2) and (3) as (4) and (5), respectively, and amended heading and text of par. (4) generally. Prior to amendment, text of par. (4) read as follows: ''Subject to the amount appropriated for a fiscal year under subsection (g) of this section, the Secretary shall, within 60 days after the end of each fiscal year beginning after September 30, 1997, adjust the establishment and product fees described in subsection (b) of this section for the fiscal year in which the adjustment occurs so that the revenues collected from each of the categories of fees described in paragraphs (2) and (3) of subsection (b) of this section shall be set to be equal to the revenues collected from the category of application and supplement fees described in paragraph (1) of subsection (b) of this section.''

Subsec. (d)(1)(C) to (E). Pub. L. 107–188, §504(d)(1), inserted ''or'' at end of subpar. (C), redesignated subpar. (E) as (D), and struck out former subpar. (D) which read as follows: ''assessment of the fee for an application or a supplement filed under section 355(b)(1) of this title pertaining to a drug containing an active ingredient would be inequitable because an application for a product containing the same active ingredient filed by another person under section 355(b)(2) of this title could not be assessed fees under subsection (a)(1) of this section, or''.

Subsec. (d)(3)(A), (B). Pub. L. 107–188, §504(d)(2), substituted ''paragraph (1)(D)'' for ''paragraph (1)(E)''.

Subsec. (f). Pub. L. 107–188, §504(e)(1), substituted ''Limitations'' for ''Assessment of fees'' in heading.

Subsec. (f)(1). Pub. L. 107–188, §504(e)(2), substituted ''In general'' for ''Limitation'' in heading and ''Fees under subsection (a) shall be refunded for a fiscal year beginning'' for ''Fees may not be assessed under subsection (a) for a fiscal year beginning'' in text.

Subsec. (g)(1). Pub. L. 107–188, §504(f)(1), which directed the amendment of par. (1) by striking ''Fees collected for a fiscal year'' and all that follows through ''fiscal year limitation.'' and inserting ''Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended.'', was not executed because the phrase ''fiscal year limitation.'' appeared in two places and because of the corrective amendment by Pub. L. 110–85, §103(h)(1), which is effective as if included in Pub. L. 107–188, §504. See 2007 Amendment note above and Effective Date of 2007 Amendment note below.

Subsec. (g)(2). Pub. L. 107–188, §504(f)(2), amended par. (2) by designating existing provisions as subpar. (A), inserting subpar. (A) heading, adding subpar. (B), redesignating former subpars. (A) and (B) as cls. (i) and (ii), respectively, of subpar. (A), substituting ''shall be retained in each fiscal year in an amount not to exceed the amount specified'' for ''shall be collected in each fiscal year in an amount equal to the amount specified'' in cl. (i), and realigning margin of cl. (ii).

Subsec. (g)(3)(A) to (E). Pub. L. 107–188, §504(f)(3), added subpars. (A) to (E) and struck out former subpars. (A) to (E) which read as follows:

''(A) $106,800,000 for fiscal year 1998;

''(B) $109,200,000 for fiscal year 1999;

''(C) $109,200,000 for fiscal year 2000;

''(D) $114,000,000 for fiscal year 2001; and

''(E) $110,100,000 for fiscal year 2002,''.

1997—Subsec. (a). Pub. L. 105–115, §103(a)(1), substituted ''Beginning in fiscal year 1998'' for ''Beginning in fiscal year 1993'' in introductory provisions.

Subsec. (a)(1)(B). Pub. L. 105–115, §103(a)(2)(A), amended heading and text of subpar. (B) generally. Prior to amendment, text read as follows:

''(i) FIRST PAYMENT.—50 percent of the fee required by subparagraph (A) shall be due upon submission of the application or supplement.

''(ii) FINAL PAYMENT.—The remaining 50 percent of the fee required by subparagraph (A) shall be due upon—

''(I) the expiration of 30 days from the date the Secretary sends to the applicant a letter designated by the Secretary as an action letter described in section 379g(6)(B) of this title, or

''(II) the withdrawal of the application or supplement after it is filed unless the Secretary waives the fee or a portion of the fee because no substantial work was performed on such application or supplement after it was filed.

The designation under subclause (I) or the waiver under subclause (II) shall be solely in the discretion of the Secretary and shall not be reviewable.''

Subsec. (a)(1)(D). Pub. L. 105–115, §103(a)(2)(B), substituted ''refused'' for ''not accepted'' in heading and ''75 percent'' for ''50 percent'', ''subparagraph (B)'' for ''subparagraph (B)(i)'', and ''refused'' for ''not accepted'' in text.

Subsec. (a)(1)(E) to (G). Pub. L. 105–115, §103(a)(2)(C), added subpars. (E) to (G).

Subsec. (a)(2). Pub. L. 105–115, §103(a)(3), reenacted heading without change and amended text generally. Prior to amendment, text read as follows: ''Each person that—

''(A) owns a prescription drug establishment, at which is manufactured at least 1 prescription drug product which is not the, or not the same as a, product approved under an application filed under section 355(b)(2) or 355(j) of this title, and

''(B) after September 1, 1992, had pending before the Secretary a human drug application or supplement,

shall be subject to the annual fee established in subsection (b) of this section for each such establishment, payable on or before January 31 of each year.''

Subsec. (a)(3)(A). Pub. L. 105–115, §103(a)(4)(A), substituted, in cl. (i), ''has been submitted for listing'' for ''is listed'' and, in closing provisions, ''Such fee shall be payable for the fiscal year in which the product is first submitted for listing under section 360 of this title, or is submitted for relisting under section 360 of this title

if the product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.'' for ''Such fee shall be payable at the time of the first such listing of such product in each calendar year. Such fee shall be paid only once each year for each listed prescription drug product irrespective of the number of times such product is listed under section 360 of this title.''

Subsec. (a)(3)(B). Pub. L. 105–115, §103(a)(4)(B), substituted ''355(j) of this title, under an abbreviated application filed under section 357 of this title (as in effect on the day before November 21, 1997), or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.'' for ''355(j) of this title.''.

Subsec. (b). Pub. L. 105–115, §103(b), amended subsec. (b) generally. Prior to amendment, subsec. (b) related to fee amounts, including a schedule of fees in par. (1) and fee exceptions for certain small businesses in par. (2).

Subsec. (c). Pub. L. 105–115, §103(c)(1), substituted ''Adjustments'' for ''Increases and adjustments'' in heading.

Subsec. (c)(1). Pub. L. 105–115, §103(c)(2), substituted ''Inflation adjustment'' for ''Revenue increase'' in heading, ''The fees and total fee revenues established in subsection (b) shall be adjusted by the Secretary'' for ''The total fee revenues established by the schedule in subsection (b)(1) shall be increased by the Secretary'' in introductory provisions, and ''change'' for ''increase'' after ''total percentage'' in subpars. (A) and (B), and inserted at end ''The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 1997 under this subsection.''

Subsec. (c)(2). Pub. L. 105–115, §103(c)(3), substituted ''September 30, 1997, adjust the establishment and product fees described in subsection (b) for the fiscal year in which the adjustment occurs so that the revenues collected from each of the categories of fees described in paragraphs (2) and (3) of subsection (b) shall be set to be equal to the revenues collected from the category of application and supplement fees described in paragraph (1) of subsection (b).'' for ''October 1, 1992, adjust the fees established by the schedule in subsection (b)(1) for the following fiscal year to achieve the total fee revenues, as may be increased under paragraph (1). Such fees shall be adjusted under this paragraph to maintain the proportions established in such schedule.''

Subsec. (c)(3). Pub. L. 105–115, §103(c)(4), substituted ''this subsection'' for ''paragraph (2)''.

Subsec. (d). Pub. L. 105–115, §103(d), struck out introductory provisions which read ''The Secretary shall grant a waiver from or a reduction of 1 or more fees under subsection (a) of this section where the Secretary finds that—'' and closing provisions which read ''In making the finding in paragraph (3), the Secretary may use standard costs.'', inserted designation, heading, and introductory provisions of par. (1), redesignated former pars. (1) to (4) as subpars. (A) to (D), respectively, of par. (1), and added pars. (1)(E), (2), and (3).

Subsec. (f)(1). Pub. L. 105–115, §103(e), substituted ''fiscal year 1997'' for ''fiscal year 1993'' and ''fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year)'' for ''fiscal year 1992''.

Subsec. (g)(1). Pub. L. 105–115, §103(f)(1), inserted at end ''Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications.''

Subsec. (g)(2)(A). Pub. L. 105–115, §103(f)(2)(A), substituted ''Acts, or otherwise made available for obligation,'' for ''Acts''.

Subsec. (g)(2)(B). Pub. L. 105–115, §103(f)(2)(B), substituted ''over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997'' for ''over such costs for fiscal year 1992''.

Subsec. (g)(3), (4). Pub. L. 105–115, §103(f)(3), added pars. (3) and (4) and struck out heading and text of former par. (3). Text read as follows: ''There are authorized to be appropriated for fees under this section—

''(A) $36,000,000 for fiscal year 1993,

''(B) $54,000,000 for fiscal year 1994,

''(C) $75,000,000 for fiscal year 1995,

''(D) $78,000,000 for fiscal year 1996, and

''(E) $84,000,000 for fiscal year 1997,

as adjusted to reflect increases in the total fee revenues made under subsection (c)(1) of this section.''

Subsecs. (i), (j). Pub. L. 105–115, §103(g), added subsec. (i) and redesignated former subsec. (i) as (j).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2017 AMENDMENT

Amendment by section 102 of Pub. L. 115–52 effective Oct. 1, 2017, with fees under this subpart to be assessed for all human drug applications received on or after Oct. 1, 2017, see section 105 of Pub. L. 115–52, set out as a note under section 379g of this title.

EFFECTIVE DATE OF 2012 AMENDMENT

Amendment by Pub. L. 112–144 effective Oct. 1, 2012, with fees under this subpart to be assessed for all human drug applications received on or after Oct. 1, 2012, see section 106 of Pub. L. 112–144, set out as a note under section 379g of this title.

EFFECTIVE DATE OF 2007 AMENDMENT

Pub. L. 110–85, title I, §103(h)(2), Sept. 27, 2007, 121 Stat. 832, provided that: ''Paragraph (1) [amending this section] shall take effect as if included in section 504 of the Prescription Drug User Fee Amendments of 2002 (Public Law 107–188; 116 Stat. 687) [amending this section].''

Amendment by Pub. L. 110–85 effective Oct. 1, 2007, with fees under this subpart to be assessed for all human drug applications received on or after Oct. 1, 2007, see section 107 of Pub. L. 110–85, set out as an Effective and Termination Dates of 2007 Amendment note under section 379g of this title.

EFFECTIVE DATE OF 2002 AMENDMENT

Amendment by Pub. L. 107–188 effective Oct. 1, 2002, see section 508 of Pub. L. 107–188, set out as a note under section 356b of this title.

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105–115 effective Oct. 1, 1997, see section 106 of Pub. L. 105–115, set out as an Effective and Termination Dates of 1997 Amendment note under section 379g of this title.

TERMINATION DATE

Section to terminate Oct. 1, 2022, see section 104(a) of Pub. L. 115–52, set out as a note under section 379g of this title.

SPECIAL RULE FOR WAIVERS AND REFUNDS

Pub. L. 105–115, title I, §103(h), Nov. 21, 1997, 111 Stat. 2304, provided that: ''Any requests for waivers or refunds for fees assessed under section 736 of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 379h) prior to the date of enactment of this Act [Nov. 21, 1997] shall be submitted in writing to the Secretary of Health and Human Services within 1 year after the date of enactment of this Act. Any requests for waivers or refunds pertaining to a fee for a human drug application or supplement accepted for filing prior to October 1, 1997 or to a product or establishment fee required by such Act for a fiscal year prior to fiscal year 1998, shall be evaluated according to the terms of the Prescription Drug User

Fee Act of 1992 [see section 101(a) of Pub. L. 102–571, set out as a Short Title of 1992 Amendment note under section 301 of this title] (as in effect on September 30, 1997) and part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379g et seq.] (as in effect on September 30, 1997). The term 'person' in such Acts shall continue to include an affiliate thereof.''

§ 379h–1. Fees relating to advisory review of prescription-drug television advertising

(a) Types of direct-to-consumer television advertisement review fees

Beginning in fiscal year 2008, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) Advisory review fee

(A) In general

With respect to a proposed direct-to-consumer television advertisement (referred to in this section as a ''DTC advertisement''), each person that on or after October 1, 2007, submits such an advertisement for advisory review by the Secretary prior to its initial public dissemination shall, except as provided in subparagraph (B), be subject to a fee established under subsection (c)(3).

(B) Exception for required submissions

A DTC advertisement that is required to be submitted to the Secretary prior to initial public dissemination is not subject to a fee under subparagraph (A) unless the sponsor designates the submission as a submission for advisory review.

(C) Notice to Secretary of number of advertisements

Not later than June 1 of each fiscal year, the Secretary shall publish a notice in the Federal Register requesting any person to notify the Secretary within 30 days of the number of DTC advertisements the person intends to submit for advisory review in the next fiscal year. Notwithstanding the preceding sentence, for fiscal year 2008, the Secretary shall publish such a notice in the Federal Register not later than 30 days after September 27, 2007.

(D) Payment

(i) In general

The fee required by subparagraph (A) (referred to in this section as ''an advisory review fee'') shall be due not later than October 1 of the fiscal year in which the DTC advertisement involved is intended to be submitted for advisory review, subject to subparagraph (F)(i). Notwithstanding the preceding sentence, the advisory review fee for any DTC advertisement that is intended to be submitted for advisory review during fiscal year 2008 shall be due not later than 120 days after September 27, 2007, or an earlier date as specified by the Secretary.

(ii) Effect of submission

Notification of the Secretary under subparagraph (C) of the number of DTC advertisements a person intends to submit for advisory review is a legally binding commitment by that person to pay the annual advisory review fee for that number of submissions on or before October 1 of the fiscal year in which the advertisement is intended to be submitted. Notwithstanding the preceding sentence, the commitment shall be a legally binding commitment by that person to pay the annual advisory review fee for that number of submissions for fiscal year 2008 by the date specified in clause (i).

(iii) Notice regarding carryover submissions

In making a notification under subparagraph (C), the person involved shall in addition notify the Secretary if under subparagraph (F)(i) the person intends to submit a DTC advertisement for which the advisory review fee has already been paid. If the person does not so notify the Secretary, each DTC advertisement submitted by the person for advisory review in the fiscal year involved shall be subject to the advisory review fee.

(E) Modification of advisory review fee

(i) Late payment

If a person has submitted a notification under subparagraph (C) with respect to a fiscal year and has not paid all advisory review fees due under subparagraph (D) not later than November 1 of such fiscal year (or, in the case of such a notification submitted with respect to fiscal year 2008, not later than 150 days after September 27, 2007, or an earlier date specified by the Secretary), the fees shall be regarded as late and an increase in the amount of fees applies in accordance with this clause, notwithstanding any other provision of this section. For such person, all advisory review fees for such fiscal year shall be due and payable 20 days before any direct-to-consumer advertisement is submitted to the Secretary for advisory review, and each such fee shall be equal to 150 percent of the fee that otherwise would have applied pursuant to subsection (c)(3).

(ii) Exceeding identified number of submissions

If a person submits a number of DTC advertisements for advisory review in a fiscal year that exceeds the number identified by the person under subparagraph (C), an increase in the amount of fees applies under this clause for each submission in excess of such number, notwithstanding any other provision of this section. For each such DTC advertisement, the advisory review fee shall be due and payable 20 days before the advertisement is submitted to the Secretary, and the fee shall be equal to 150 percent of the fee that otherwise would have applied pursuant to subsection (c)(3).

(F) Limits

(i) Submissions

For each advisory review fee paid by a person for a fiscal year, the person is enti-